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Volume 64 Number 3

SURGERY

CONTENTS, SEPTEMBER 1968

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CLINICAL SURGERY

page 529 **Traumatic diaphragmatic hernia.** Marvin Pomerantz, M.D., Bradley M. Rodgers, M.D., and David C. Sabiston, Jr., M.D., Durham, N. C.

535 **Primary esophageal adenocarcinoma: Report of 16 cases.** Jean-Louis Lortat-Jacob, M.D., J. N. Maillard, M.D., Cl. A. Richard, M.D., F. Fékété, M.D., Michel Huguier, M.D., and Jacqueline Conte-Marti, M.D., Clichy (Seine), France

544 **Blood flow after reconstructive arterial surgery measured by implanted electromagnetic flow probes.** Stuart Renwick, M.B. (Sydney), F.R.C.S., F.R.A.C.S., Ivor T. Gabe, M.D., M.R.C.P., J. P. Shillingford, M.D., F.R.C.P., and Peter Martin, V.R.C., M.Chir.(Cantab.), F.R.C.S., London, England

554 **A simple and safe coronary perfusion line: Gravity and overflow system.** Shoji Eguchi, M.D., Hideo Matsuzawa, M.D., and Ken-Ichi Asano, M.D., Niigata, Japan

556 **Eversion proctectomy.** Sidney Lipton, M.D., and Felix A. Siegman, M.D., Brooklyn, N. Y.

558 **Duodenoscopy: An aid for investigation of the complete duodenum.** George E. Miller, Jr., M.D., Sacramento, Calif.

560 **Esophageal retractor for hiatal hernia repair.** C. Doyle Haynes, M.D., Atlanta, Ga.

562 **Intra-abdominal vascular injury.** Garland D. Perdue, Jr., M.D., and Robert B. Smith, III, M.D., Atlanta, Ga.

569 **The solitary aortoiliac lesion.** T. W. Staple, M.D., St. Louis, Mo.

SURGICAL EDUCATION

577 **The general surgeon and the curriculum.** James D. Hardy, M.D., Jackson, Miss.

582 **General surgery versus specialty training at a graduate level.** William S. Blakemore, M.D., Philadelphia, Pa.

continued on page 3

page 587 **The role of the surgical specialties in medical education.** J. Hartwell Harrison, M.D., Thomas B. Quigley, M.D., and Warren J. Taylor, M.D., Boston, Mass.

595 **The academic surgical arena, past and present: A tribute to Evarts Graham, great surgical leader and innovator.** Owen H. Wangensteen, M.D., Minneapolis, Minn.

INVESTIGATIVE SURGERY

605 **Effect of aluminum suture on wound healing: Long-term comparative study on the tensile strength and hydroxyproline content.** Kwang-Tzen Wu, M.D., Paramjeet S. Chopra, M.D., and Philip N. Sawyer, M.D., Brooklyn, N. Y.

610 **The suppression of experimental wound infections by biocidal sutures.** Harry H. LeVeen, M.D., Gerald Falk, B.S., Frank A. Mazzapica, B.S., and Clarence Dennis, M.D., Ph.D., Brooklyn, N. Y.

614 **The mammalian homologue of the avian bursa of Fabricius. I. Neonatal extirpation of Peyer's patch-type lymphoepithelial tissues in rabbits: Method and inhibition of development of humoral immunity.** D. Y. Perey, M.D., M. D. Cooper, M.D., and R. A. Good, M.D., Ph.D., Minneapolis, Minn.

622 **Evaluation of biochemical changes associated with experimental endotoxemia. II. Lactic dehydrogenase activity.** H. Kenneth Sleeman, Ph.D., Paul B. Jennings, Captain, VC, USA, Clarence E. Emery, B.S., and Harold F. Hamit, Colonel, MC, USA, Washington, D. C.

629 **Hyperkalemia accompanying canine portal venous occlusion.** J. Bergan, M.D., E. Teixeira, M.D., H. Yu, M.D., W. Clarke, M.D., and M. Coburn, M.D., Chicago, Ill.

634 **A filtering device for the prevention of particulate embolization during the course of cardiac surgery.** A. Moneim Fadali, M.D., D.S., M.S., Stephen R. Topaz, B.S.M.E., M. Mel Ameli, M.D., and Vincent L. Gott, M.D., Baltimore, Md.

640 **The influence of mannitol on toxic reactions to contrast angiography.** Harold E. Snyder, M.D., Duncan, A. Killen, M.D., and John H. Foster, M.D., Nashville, Tenn.

643 **The nature and significance of the thoracic duct-subclavian vein junction.** R. Randolph Bradham, M.D., and Timothy Takaro, M.D., Charleston, S. C., and Oteen, N. C.

647 **Experimental aortic valve homotransplantation without cardiopulmonary bypass.** Robert W. Barnes, M.D., Hitoshi Mohri, M.D., Dr. Med. Sci., and K. Alvin Merendino, M.D., Ph.D., Seattle, Wash.

continued on page 5

CONTENTS *continued*

page 653 **Responses to isoproterenol and THAM during experimental hemorrhagic shock.** Kenneth A. Myers, M.B., B.S. (Melbourne), Harold A. Paul, M.D., and Ormand C. Julian, M.D., Ph.D., Chicago, Ill.

PEDIATRIC SURGERY

661 **The various patterns of intestinal atresia.** Rowena Spencer, M.D., New Orleans, La.

669 **Familial incidence of congenital anorectal anomalies.** F. Cozzi, M.D., and A. W. Wilkinson, Ch.M. (Edin.), F.R.C.S.E., F.R.C.S., London, England

672 **Renovascular hypertension in childhood.** Arnold G. Coran, M.D., and Samuel R. Schuster, M.D., Boston, Mass.

REAPPRAISAL

678 **Ileostomy.** Bryan N. Brooke, M.D., F.R.C.S., London, England

SURGICAL TECHNIQUES

681 **Crossover femoropopliteal shunt.** Robert H. Goetz, M.D., F.A.C.S., and Jere W. Lord, Jr., M.D., F.A.C.S., Bronx and New York, N. Y.

SURGICAL HISTORY

685 **History of blood transfusion: A tercentennial look.** Peter Hutchin, M.D., Chapel Hill, N. C.

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A filtering device for the prevention of particulate embolization during the course of cardiac surgery

A. MONEIM FADALI, M.D.,
D.S., M.S.
STEPHEN R. TOPAZ, B.S.M.E.
M. MEL AMELI, M.D.
VINCENT L. GOTT, M.D.
BALTIMORE, MD.
From the Department of Surgery, The Johns Hopkins University School of Medicine

The occurrence of embolization during the course of surgical treatment of mitral stenosis continues to be a matter of considerable concern. This problem has been greatly lessened with the advent of the pump oxygenator and the availability of the open commissurotomy. However, for various reasons, embolization during commissurotomy has not been eliminated. Many hospitals throughout the world have cardiovascular surgical units capable of doing a closed mitral commissurotomy but they are, in turn, unable to provide a pump oxygenator on a standby basis in case thrombus is encountered within the heart. Although the main incidence of embolization would be expected in these closed cases, there still exists a low incidence of particulate embolization in patients undergoing direct-vision surgery for mitral valve disease. This can result either from a thrombus dislodged during removal from the left atrium or from calcific emboli loosened during excision of a diseased mitral valve.

In an effort to prevent embolization during mitral commissurotomy, the authors have developed a filtering device which can be placed in the ascending aorta at the time of surgery. This device is designed to catch particulate emboli and yet not interfere with the flow of blood in the proximal aorta.

THE INITIAL FILTERING DEVICE (PARACHUTE DESIGN)

The initial device was constructed of polypropylene mesh of 0.7 mm. mesh size and had the configuration of a "parachute" (Fig. 1). It was 4 cm. long and its proximal and distal parts were made radiopaque.

METHOD

Fifteen heparinized mongrel dogs weighing 30 to 50 pounds were anesthetized with Nembutal, and, after initiating support with a mechanical respirator, the left chest was entered through the fifth interspace. The pericardium was opened and 2 polyethylene tubes (3 mm. I.D.) were introduced into the left atrium and secured by a purse-string suture. One tube permitted the injection of 20 c.c. of 70 percent Hypaque to visualize the aorta, and the other tube served as a conduit for injecting radiopaque emboli into the left atrium. These emboli were made of silicone rubber 501* with 50 percent barium sulfate. They were cylindrical in shape, 1.3 mm. in diameter, and had a specific gravity of approximately one. These silicone rubber emboli were molded within a perforated electrical printed circuit board with appropriate sized holes. The silicone rubber was spread over this board and into the many perforations. After 24 hours, the molded silicone emboli were pushed out of the molding

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*Silastic RTV 501 from the Dow Corning Corporation, Midland, Mich.

Vol. 64, No. 3, pp. 634-639

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3, pp. 634-639

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ward with a blunt needle and stored for eventual use.

With a graduated metal trocar (Fig. 1), the filter device was introduced through a small stab incision in the apex of the left ventricle into the ascending aorta so that the inflow end of the device was proximal to the brachiocephalic artery. The position of the filter was confirmed by feeling the tip of the introducer and also by examining the aortograms done at the time the device was introduced. To prevent the filter from traveling downstream after positioning (Case 6, Table I), a small alligator clamp was applied to the tethering sutures as they emerged from the ventricle.

Twenty emboli were then injected into the left atrium, and x-ray films were subsequently taken of the whole animal to determine the distribution of emboli that might have bypassed the filter. The device was then carefully removed from the aorta and heart, and the number of trapped emboli were counted. Also, in some cases, dissection studies were done to locate peripheral emboli. The integrity of the aortic and mitral valves was grossly checked in every animal and, in some cases, microscopic sections were obtained of the aortic wall.

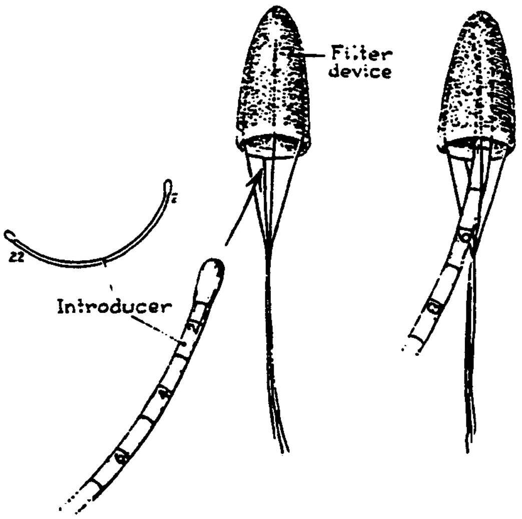

Fig. 1. Diagram showing the parachute filter and the metal introducer.

RESULTS

The percentage of emboli caught within the parachute device ranged between 60 and 100 percent with an average of 75 percent (Table I). Of a total of 270 emboli injected, 66 (25 percent) bypassed the filter (Table I). It was found that introduction and extraction of this device was fairly easy, and no damage was noted to the aortic or mitral valve in any of the animals. Also, no coronary emboli were encountered in any of these studies.

Two interesting cases in this series require further discussion. In Case 6, the device migrated down the aorta as an embolus and so, subsequently, a small alligator clamp was applied to the tethering sutures as they emerged from the ventricle. In Case 8, the mouth of the device did not open completely (as judged radiologically), and thus all of the emboli were lost into the systemic circulation.

Because a moderate number of the emboli bypassed this initial filtering device, a second type of filter was constructed and is described below.

THE CURRENT FILTERING DEVICE (UMBRELLA DESIGN)

The second type of filtering device has the configuration of an umbrella (Fig. 2) with 8 ribs of stainless steel spring wire No. 303

Table I. *Collective results in the whole series*

Type of filter	*No. of experiments*	*No. of injections*	*Total No. of emboli injected*	*Total No. of emboli trapped*	*% of emboli trapped*	*% of emboli that bypassed the filter*
Parachute filter	15	14	270	204	75.0	25.0
Umbrella filter	20	56	570	555	97.4	2.6

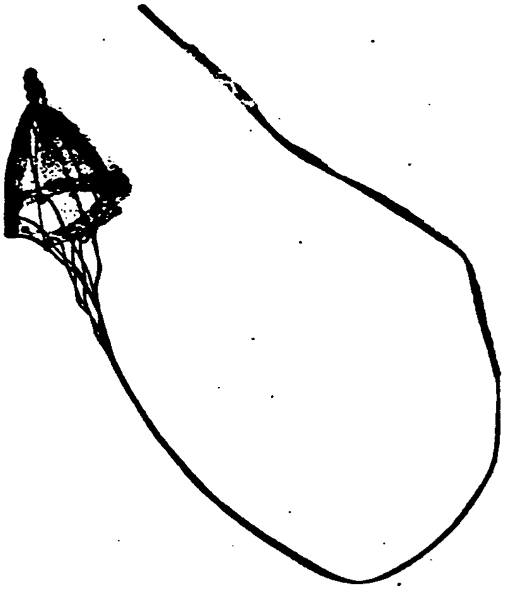

Fig. 2. The umbrella filter in the open position. An uncoated device is depicted because the rib mechanism can be better illustrated.

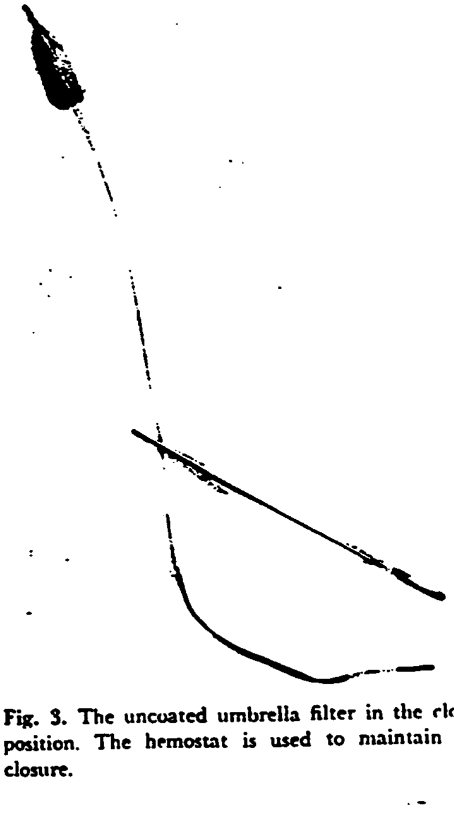

Fig. 3. The uncoated umbrella filter in the closed position. The hemostat is used to maintain this closure.

(0.015 diameter). The stainless steel ribs provide a very good spring action which permits the umbrella to adapt to various aortic dimensions. The ribs of the umbrella were covered with nylon cloth with a 0.7 mm. mesh size. Eight silk sutures were attached to the mouth of the device and were brought together in a confluence. By pulling on the confluence of sutures within a polyethylene tube, closure of the umbrella could be effected (Fig. 3).

METHOD

In 20 mongrel dogs, weighing 35 to 50 pounds, a small stab incision was made in the apex of the left ventricle, and a Gerbode dilator was used to grasp the tip of the umbrella filter and introduce it through the ventricular wall. The device was then guided up to the required position in the ascending aorta, and the dilator was removed from the heart. The clamp holding the polyethylene tube was then released, and the filter was allowed to open and adjust itself to the inner wall of the aorta (Fig. 4). Emboli were then injected into the left atrium, and x-rays were taken in the usual manner (Fig. 5). Several injections of emboli were carried out in each case, and, after introduction of all the emboli, the filter was closed and removed from the heart.

In every case, the emboli that were caught in the filter were counted and the aortic and mitral valves were inspected for damage. In 5 animals, histologic sections were made of the aortic segment which was in contact with the device. In 3 cases the pressure was recorded in the aorta proximal and distal to the filter to see if a significant pressure gradient existed. In 15 dogs, systemic heparin was administered to prevent clot formation on the device, while in the final 5 dogs, a graphite-benzalkonium-heparin coating was utilized to prevent thrombus formation on the device.

RESULTS

In 20 experiments, the umbrella device trapped between 90 and 100 percent of the emboli with an average of 97.4 percent en-

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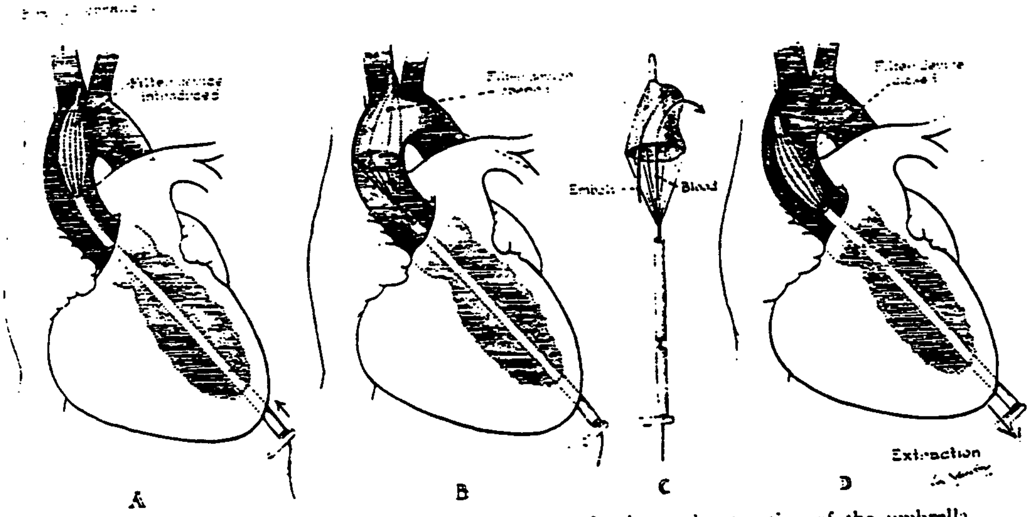

Fig. 4. Diagrams showing the various stages of introduction and extraction of the umbrella filter.

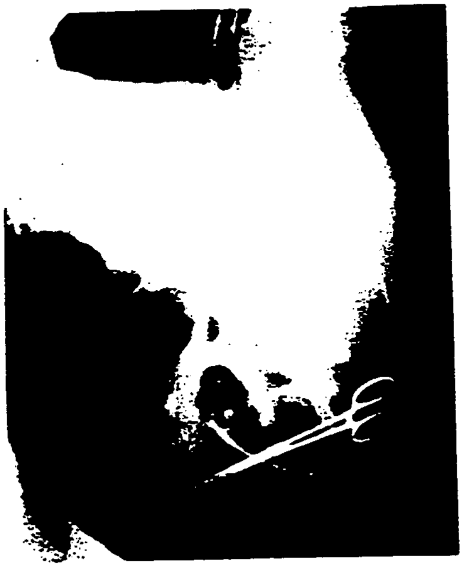

Fig. 5. Angiocardiogram showing the umbrella filter in the ascending aorta with the radiopaque silicone emboli trapped in the downstream cul-de-sac.

trapment. The total number of emboli injected in this series was 570 and only 15 emboli or 2.6 percent bypassed the filter (Table I). The nylon mesh of the device was redundant and tended to form a distal cul-de-sac so that the emboli would usually collect at this site. It is our opinion that this feature does not permit a retrograde movement of the emboli back to the coronary artery orifices during diastole. However, because of potential embolization to the coronary vessels, a small inner truncated cone of the same nylon mesh was added so that any emboli would be held between the two layers of mesh and not carried backward during diastole.

With the use of this umbrella device, both the introduction and extraction were relatively easy and, in every case, both the aortic and mitral valves were found to be undamaged. In addition, the heart action remained satisfactory, and there was no significant pressure gradient across the umbrella. Gross inspection in every case and histological examination in 5 cases showed no local aortic wall damage of any kind. Also, no coronary emboli were found in any of these cases. The use of graphite-benzalkonium-heparin coated[5] filters in 5 dogs demonstrated that systemic heparinization may be omitted if such a thromboresistant coating is employed. These filters always appeared to be free of thrombus or fibrin at the completion of the experiment. Finally, with the device in its usual aortic position, a procedure simulating mitral commissurotomy was carried out in 5 dogs. This did not lead to the dissemination of any emboli that were already caught in the filter, and the presence of the device in the heart did not interfere with the procedure on the mitral valve.

DISCUSSION

There are many articles in the surgical literature which have detailed the factors relating to embolization during mitral commissurotomy.[4, 7] The incidence of embolization during or after surgery has varied in these reports from about 15 percent in fibrillating patients to about 3 percent in nonfibrillating[1, 3, 8] patients, and each author has suggested a manipulative technique designed to reduce the incidence of this serious complication. These include compression of the carotid arteries in the neck,[6] clamping of the innominate artery,[1] or clamping the left common carotid and innominate arteries for periods up to 60 seconds each as suggested by Bolton and associates[2] in 1954. In Bailey's experience, this reduced the incidence of cerebral emboli from 5 percent to 2.3 percent but at the expense of increasing peripheral embolism. Logan[7] advocated clamping the 3 branches of the aortic arch for periods up to 40 seconds, but this procedure did not decrease the incidence of cerebral embolism. Preoperative anticoagulation therapy was advised by Strom and Hansen[12] in 1955, Glenn[1] in 1960, and by Miscall[10] in 1962.

Table II. *Regional distribution of emboli that bypassed the filter devices*

Region	*Number of emboli* *Parachute filter*	 *Umbrella filter*
Brain	15	0
Heart	0	0
Neck	4	0
Chest	2	0
Right foreleg	10	0
Left foreleg	8	5
Right hindleg	7	5
Left hindleg	8	3
Viscera	9	0
Not found	3	2
Total number	66	15

The results of administering anticoagulants preoperatively in cases where thrombus in the left atrium is anticipated have been conflicting and the complications associated with their administration were reported to be approximately 15 percent. About one third of these complications were major and consisted mainly of bleeding from the chest wound and the gastrointestinal tract, as well as retinal and cerebral hemorrhage.[4] Obviously, anticoagulants do not offer any help to the group of patients with calcified valves who constitute at least one fourth of the patients undergoing surgery. In this latter group, the incidence of embolism is about 8 percent.[11]

These various procedures to prevent embolization were not always satisfactory and hence many authors shifted to open-heart surgery for mitral commissurotomy in the cases where systemic embolization seemed likely. Instances of embolization, however, still occurred during open-heart surgery from thrombi within the left atrium or from a heavily calcified mitral valve.[8]

The present work demonstrates that an umbrella-shaped filter is capable of trapping 97.4 percent of the injected artificial emboli. Also, the presence of the umbrella near the origin of the cerebral vessels seems to offer a nearly total protection from cerebral embolism (Table II). This is a grave complication which is attended clinically with a mortality rate as high as 80 percent. Although our primary aim was to protect the brain, the device seemed to also offer a large measure of protection to the viscera and limbs (Table II). The absence of coronary emboli during the experiments was also gratifying.

The filtering device was easily passed in and out of the left ventricular cavity and ascending aorta. This, to a large extent, prevented any damage to the aortic and mitral valves. The results obtained suggest that the mesh dimensions of the filter were large enough to allow an unimpeded blood flow and, at the same time, small enough to trap

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tiny emboli. It was found during these studies that the spring action of the stainless steel ribs was dependable and could not be satisfactorily duplicated by plastic ribs. This spring action permitted the umbrella to be adaptable to the vessel and, therefore, to filter practically all of the blood flowing through the ascending aorta.

Although this filter device should have greatest application during closed mitral commissurotomy, it could also be used in those "open" operations in which there is a possibility of embolization of calcium or thrombus to peripheral sites. This latter problem has not been completely eliminated with current preventive techniques.

SUMMARY AND CONCLUSIONS

A device having the configuration of an umbrella has been used experimentally to filter systemic blood while injecting emboli into the left atrium. Experiments carried out on mongrel dogs showed that an average of 97.4 percent of these emboli were trapped by the device. No coronary emboli were reported in these experiments, and the integrity of the aortic wall and aortic and mitral valves was not disturbed. The device does not offer resistance to blood flow and can be used without systemic heparinization. We suggest its clinical use in the course of closed mitral commissurotomy if embolization is expected to occur, particularly in centers where there is no ready access to cardiopulmonary bypass.

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